REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

I. Amendment and reply after final

Applicant acknowledges that this Amendment and Reply is submitted after a final rejection, and is accompanied by a Declaration and Exhibits A-D. The Declaration is complying with any requirement of form expressly set forth in a previous Office Action." 37 C.F.R. § 1.116(b)(1). Of Exhibits A-D, Exhibit A is merely an entry from GenBank, and Exhibits B-D are references cited in the specification. The amendments add no new matter, requires no new search, and should be entered and considered.

II. Status of the claims

Claims 1-19, 22-42 were previously withdrawn, and claims 20, 21 and 44 were previously cancelled. Claim 43 is amended to remove the definite article "the" in the context of IL-6 biological activity, and to correct a minor typographical error. No new matter is added. This amendment is made solely to advance prosecution and not in acquiescence to any rejection. After the foregoing amendments, claims 1-19, 22-43 and 45-47 are pending, with claims 43 and 45-47 under examination.

III. Rejection under the enablement provision of 35 U.S.C. 112, first paragraph

A. Biological Deposit

Claims 43 and 45-47 are rejected as allegedly lacking in enablement for failure to satisfy the biological deposit requirements under 37 C.F.R. §§ 1.801- 1.809 for FERM BP-2232. Office Action at pages 3-4. Applicant provides herewith a Declaration of Biological Deposit for FERM BP-2232, as requested by the Examiner. This aspect of the rejection is believed to be overcome.

B. Scope of enablement

Claims 43 and 45-47 are also rejected for allegedly exceeding the scope of enablement provided by the specification in "administering 'all' interleukin-6 receptor antibodies which

bind to human IL-6" Office Action at page 5. The rejection relies on the Examiner's interpretation of "human interleukin-6 receptor encoded by the cDNA contained in the plasmid pIBIBSF2R deposited as FERM BP-2232" (recited in claim 43) to encompass gp130 as well as IL-6R (CD126). The specification provides working examples with PM-1 and MR-16, which are antibodies against IL-6R (CD126), but does not provide working examples for antibodies against gp130. Following the Examiner's reasoning, claims that read on methods of treatment that use antibodies against gp130 are not enabled. Applicant respectfully traverses because the claims read only on methods of treatment that use antibodies against IL-6R (CD126).

1. Applicant may be his/her own lexicographer

MPEP § 2111 requires that "the pending claims must be '"given their broadest reasonable interpretation consistent with the specification,' " but that "[t]he broadest reasonable interpretation of the claims 'must also be consistent with the interpretation that those skilled in the art would reach.' *In re Cortright,* 165 F.3d 1353, 1359, 49 USPQ2d 1464, 1468 (Fed. Cir. 1999). MPEP § 2111.01 notes that "the ordinary and customary meaning of a term may be evidenced by a variety of sources, including "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." *Phillips v. AWH Corp.*, 415 F.3d at 1314 (Fed. Cir. 2005)."

Where a particular term differs from an ordinary and customary meaning, "[a]n applicant is entitled to be his or her own lexicographer and may rebut the presumption that claim terms are to be given their ordinary and customary meaning by clearly setting forth a definition of the term that is different from its ordinary and customary meaning(s)." MPEP § 2111.01, which refers to *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994) (inventor may define specific terms used to describe invention, but must do so "with reasonable clarity, deliberateness, and precision" and, if done, must " 'set out his uncommon definition in some manner within the patent disclosure' so as to give one of ordinary skill in the art notice of the change" in meaning).

Applicant's asserted construction of the claims is consistent with the specification, extrinsic sources, and the biological deposit.

2. The specification

The Examiner's view that "IL-6 receptor" should be read to encompass both the IL-6 receptor *per se* (CD126) and gp130 is contrary to the specification. The "Background of the Invention" on page 1 states:

> IL-6 transmits its biological signal through two proteins on the cell. One of them is IL-6 receptor, a IL-6 binding protein with a molecular weight of about 80 kD, (Taga, T et al., J. Exp. Med. (1987) 166, 967-981; Yamasaki, K. et al., Science (1987) 241, 825-828). IL-6 receptor exists not only in the membrane-bound form with transmembrane domain expressed on the cell surface but also as a soluble IL-6 receptor consisting mainly of the extracellular region. The other is a membrane-bound protein gp130 having a molecular weight of about 130 kD that is involved in non ligand binding signal transduction. IL-6 and IL-6 receptor form the IL-6/IL-6 receptor complex, which after binding to gp130 transmits its biological signal to the cell (Taga, T. et al., Cell (1989) 58, 573-581)

The distinction between CD126 and gp130 is made throughout the specification. For example, page 2, lines 4 to 10, refers to anti IL- 6 receptor antibody (*i.e.* antibody against IL-6 receptor) and anti-gp130 antibody *(i.e.* antibody against gp130) as different antibodies.

It is clear to a person of ordinary skill in the art that "IL-6 receptor" corresponds to the IL-6 α subunit (CD126), and does not correspond to IL-6 receptor β subunit (gp130). To interpret "IL-6 receptor" to encompass gp130 is contrary to the clear meaning and intent evident through the specification, and contrary to MPEP § 2111.

Even *if* the *plain meaning* of the claims allows "IL-6 receptor" to encompass gp130, to assert that the plain meaning controls is contrary to the MPEP and law which permits Applicant to be his or her own lexicographer. Because the specification makes clear that Applicant intends "IL-6 receptor" to read on CD126, and clearly distinguishes this from gp130, Applicant has met the requirement that such alternative meaning is "set out . . .in some manner within the patent disclosure so as to give one of ordinary skill in the art notice of the change in meaning." *In re Paulsen*, 30 F.3d 1475. Accordingly, Applicant's asserted interpretation controls even if the Examiner can demonstrate an alternative plain meaning.

3. Extrinsic sources of evidence

Applicant may also rely on extrinsic sources. MPEP § 2111, *Phillips v. AWH Corp.*, 415 F.3d at 1314 (Fed. Cir. 2005). To this end, **Exhibit A** is a GenBank entry for the IL-6 receptor which lists, INTERLEUKIN 6 RECEPTOR, ALPHA (IL6RA) and CD126 as other names of INTERLEUKIN 6 RECEPTOR (IL6R). It is clear that Applicant's meaning is not only consistent with extrinsic sources, but that the extrinsic sources mandate that the term "IL-6 receptor" means IL-6 receptor α subunit (CD126) unless indicated otherwise.

Exhibits B-D are referenced on page 1 of the specification, and describe research identifying and isolating IL-6 receptor, and distinguishing it from gp130. More particularly, **Exhibit B** (Taga *et al.*, *J. Exp. Med.* (1987) 166, 967-981) identifies the IL-6 receptor. **Exhibit C** (Yamasaki, *et al.*, *Science* (1987) 241, 825-828) describes the cloning of the IL-6 receptor. IL-6 receptor exists not only in the membrane-bound form with transmembrane domain expressed on the cell surface but also as a soluble IL-6 receptor consisting mainly of the extracellular region. This is distinguished from gp130, described in **Exhibit D** (Taga, *et al. Cell* (1989) 58, 573-581), as membrane-bound, having a different molecular weight, and involved in non-ligand binding signal transduction. The combination of gp130 and CD126 is an IL-6 receptor *complex*, in comparison to IL-6 receptor *per se* (CD126).

Furthemore, the Genbank entry submitted herein as Exhibit A also references Exhibit C (concerning IL-6 receptor/CD126), but *not* Exhibit D (concerning gp130).

Therefore, the Examiner's view that an anti-IL-6 receptor antibody covers an anti-gp130 antibody does not conform to the description in the specification or extrinsic sources.

4. Declaration of Biological Deposit for FERM BP-2232

MPEP § 2163 states that:

> Deposit of Biological Materials for Patent Purposes, Final Rule, 54 FR 34,864 (August 22, 1989), ("The requirement for a specific identification is consistent with the description requirement of the first paragraph of 35 U.S.C. 112, and to provide an antecedent basis for the biological material which either has been or will be deposited before the patent is granted.") Id. at 34,876. "The description must be sufficient to permit verification that the deposited biological material is in

> fact that disclosed. Once the patent issues, the description must be sufficient to aid in the resolution of questions of infringement." Id. at 34,880.). Such a deposit is not a substitute for a written description of the claimed invention. The written description of the deposited material needs to be as complete as possible because the examination for patentability proceeds solely on the basis of the written description. See, e.g., In re Lundak, 773 F.2d 1216, 227 USPQ 90 (Fed. Cir. 1985). See also 54 FR at 34,880 ("As a general rule, the more information that is provided about a particular deposited biological material, the better the examiner will be able to compare the identity and characteristics of the deposited biological material with the prior art."

The MPEP and the USPTO thus recognize that a deposit of biological material serves not only to provide written description, but aid in defining claim scope, a position consistent with the reasoning in *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F. 3d 1316 (Fed. Cir. 2002).

With the accompanying submission of the Declaration of Biological Deposit for FERM BP-2232, Applicant has complied with all biological deposit requirements and thus may use reference to FERM BP-2232 as a basis for defining the claims.

The evidence demonstrates that FERM BP-2232 encodes IL-6R (CD126), and not gp130. First, a person of ordinary skill may obtain FERM BP-2232 from the depository, isolate the plasmid and sequence the insert, and thereby confirm that that it encodes IL-6R (CD126), and not gp130. Second, one may refer to U.S. Patent No. 5,171,840, which references BP-2232 (col. 12, line 60 to col. 13, line 2), and which describes, and claims, IL-6R (CD126) in distinction from gp130. The sequence described and claimed in U.S. Patent No. 5,171,840 also matches that found in Exhibit A, the GenBank entry for the IL-6 receptor, which further refers to Exhibit C which is cited in the specification as "IL-6 receptor," and is distinguished from gp130.

5. Summary

Applicant's specification, cited art, and biological deposit all point to the "IL-6 receptor" recited in the claims as being IL-6 α subunit (CD126), and not IL-6 receptor β subunit (gp130). With such a construction, the claims do not exceed the scope of the enablement provided by the specification, which provides at least two working examples,

PM-1 and MR-16. Applicant respectfully requests reconsideration and withdrawal of the rejection.

IV. Rejection under 35 U.S.C. § 112, second paragraph

Claim 43 is rejected as indefinite for use of the definite article "the," and claims 45-47 are rejected as depending from claim 43. Office Action at pages 7-8. Claim 43 has been amended to remove the definite article, removing the basis of the indefiniteness rejection. Reconsideration and withdrawal is requested.

V. Rejections under 35 U.S.C. §§ 102(b), 103(a)

Claims 43 and 45-47 are rejected as allegedly anticipated by WO 96/38481, and allegedly obvious over the combination of WO 96/38481 and Queen *et al.* (U.S. Patent No. 5,530,101). Office Action at pages 8-11. The basis of both rejections is that (a) the "IL-6 receptor" recited in the claims is asserted to encompass both the IL-6 receptor *per se* and gp130 and (b) WO 96/38481 allegedly discloses antibodies which bind to, and inhibit, gp130. Applicant respectfully traverses.

As set forth above (§ III(B)), Applicant has shown that the IL-6 receptor "encoded by the cDNA contained in the plasmid pIBIBSF2R deposited as FERM BP-2232" (as recited in claim 43), encodes the IL-6 receptor *per se* (*i.e.* CD126) and not gp130. Applicant believes that the rejections under 35 U.S.C. §§ 102(b), 103(a) are overcome and should be withdrawn.

CONCLUSION

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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